REMARKS

Status of the Claims

Claims 13-24 are pending in the present application and are subject to restriction requirement.

Claim 13, 22, 23, and 24 are amended herein to more clearly define the claimed invention. More specifically, claims 13 is amended herein to recite a method of alleviating the degeneration of ocular cells "due to an ocular disease"; claim 22 is amended herein to recite a method of alleviating the degeneration of ocular cells "due to an ocular disease"; claim 23 is amended herein to recite a method of "treating" an ocular wound after surgery and to recite expression of said exogenous nucleic acid in said ocular "cell"; claim 24 is amended to recite a method of "treating " an ocular wound and to recite expression of said nucleic acid in said ocular "cell". Support for the amended claims can be found throughout the specification, *e.g.*, see page 1, line 9 to page 3, line 12; and page 15, line 6 to page 17, line 12. Therefore, no new matter has been added by way of the amendments herein.

Interpretation of the Claims

The Office Action alleges that in claim 13, and claims 14-21 dependent therefrom, the preamble and body of the claim are not consistent. Thus, for the purposes of compact prosecution, claims 13-21 are interpreted as a method of alleviating the degeneration of ocular cells in a genetic ocular disease. To more clearly define the claimed invention, claim 13, and claims 14-21 dependent therefrom, are amended herein to recite a method of alleviating the degeneration of ocular cells "due to an ocular disease".

The Office Action further alleges that the preamble and body of claim 22 is not consistent and, thus, for purpose of compact prosecution, claim 22 is interpreted as a method of alleviating the degeneration of ocular cells in an ocular lysosomal storage disease. To more clearly define the invention, claim 22 is amended herein to recite a method of alleviating the degeneration of ocular cells "due to an ocular disease," wherein the ocular disease is lysosomal storage disease.

As stated above, support for the amended claims can be found throughout the specification, *e.g.*, see page 1, line 9 to page 3, line 12; and page 15, line 6 to page 17, line 12. Therefore, no new matter has been added by way of the amendments herein. In view of the amendments and remarks herein, Applicant submits that the preamble and body of claim 13, claims 14-21 dependent therefrom, and claim 22, are consistent, and the claims are clearly defined.

Restriction Under 35 U.S.C. § 121

The Office Action alleges that the application claims three independent and distinct inventions, designated Groups I-III and, therefore, pursuant to 35 U.S.C. § 121, requires restriction to one of the three inventions. For the reasons given below, Applicant submits that the restriction is improper and respectfully requests withdrawal of the restriction requirement. However, in conformity with the requirements of 37 C.F.R. § 1.143, Applicant provisionally elects Group I, with traverse.

The Office Action alleges the following three inventions: Group I, claims 13-21, a method of alleviating the degeneration of ocular cells in a genetic ocular disease, wherein the method comprises contacting an ocular cell *in situ* using an exogenous nucleic acid encoding a protein associated with the ocular disease under conditions for the direct uptake of the nucleic acid and whereby the nucleic acid is expressed in the ocular cell; Group II, claim 22, a method of alleviating the degeneration of ocular cells in an ocular disease, using an exogenous nucleic acid encoding a protein associated with the ocular disease, wherein the disease is lysosomal storage disease; and Group III, claims 23 and 24, a method of alleviating an ocular wound or alleviating an ocular wound after surgery using an exogenous nucleic acid encoding a protein useful in alleviating the ocular wound. Further, the three alleged inventions share a single identical class and subclass, *i.e.*, class 514, subclass 44.

The Office Action asserts that Groups I-III are distinct inventions because: 1) one group is allegedly not required for the other; 2) each group allegedly requires different starting materials, *e.g.*, a patient with the recited genetic ocular disease or ocular wound and

different therapeutic end points; and 3) each group allegedly has different search requirements therefore a search and/or would be unduly burdensome for the Examiner.

The two criteria for a proper restriction requirement between patentably distinct inventions are: 1) the inventions must be independent or distinct as claimed; and 2) there must be a serious burden on the examiner if restriction is required (MPEP Section 803). [*Emphasis added.*]

Applicant submits that the second criteria has not been satisfied and, thus, the restriction requirement is not proper. The claims as amended herein are directed to methods of alleviating the degeneration of ocular cells due to an ocular disease (claims 13-22); a method of treating an ocular wound after surgery (claim 23); and a method of treating an ocular wound (claim 24). The alleged inventions belong to a single and identical subclass (*i.e.*, class 514, subclass 44). Thus, examination of claims 13-24 does not require a different field of search and the search that is required for one group is required for the other two groups. Thus, Applicant submits that there is no serious burden on the Examiner to examine claims 13-24 as a whole and, further, both criteria for a proper restriction requirement have not been satisfied.

In addition, for the same reasons stated above, Applicant submits that further restriction based on the election of the invention of Group I is improper.

In view of the above amendments and remarks, Applicant respectfully requests withdrawal of the restriction.

CONCLUSION

In view of the foregoing, Applicant submits that claims 13-24 are in condition for allowance. Therefore, issuance of a formal Notice of Allowance is respectfully requested.

Respectfully submitted,

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MARKED-UP VERSION OF THE PENDING CLAIMS

13. (Twice Amended) A method of alleviating the degeneration of ocular cells due to an ocular disease, said method comprising directly contacting an ocular cell *in situ* with an exogenous nucleic acid under conditions permissive for the direct uptake of said exogenous nucleic acid, said exogenous nucleic acid encoding a protein associated with said ocular disease, whereby said exogenous nucleic acid is expressed in said ocular cell.

14. The method of claim 13, and wherein said genetic ocular disease is autosomal retinitis pigmentosa.

15. The method of claim 13, and wherein said genetic ocular disease is autosomal dominant retinitis punctata albescens.

16. The method of claim 13, and wherein said genetic ocular disease is butterfly-shaped pigment dystrophy of the fovea.

17. The method of claim 13, and wherein said genetic ocular disease is adult vitelliform macular dystrophy.

18. The method of claim 13, and wherein said genetic ocular disease is Norrie's disease.

19. The method of claim 13, and wherein said genetic ocular disease is blue cone monochromasy.

20. The method of claim 13, and wherein said genetic ocular disease is choroideremia.

21. The method of claim 13, and wherein said genetic ocular disease is gyrate atrophy.

22. (Twice Amended) A method of alleviating the degeneration of ocular cells due to an ocular disease, said method comprising directly contacting an ocular cell *in situ* with an exogenous nucleic acid under conditions permissive for the direct uptake of said exogenous nucleic acid, said exogenous nucleic acid encoding a protein associated with said ocular disease, whereby said exogenous nucleic acid is expressed in said ocular cell, wherein said disease is lysosomal storage disease.

23. (Once Amended) A method of [alleviating] treating an ocular wound after surgery, said method comprising directly contacting an exogenous nucleic acid and an ocular cell *in situ* under conditions permissive for the direct uptake of said exogenous nucleic acid by said ocular cell, whereby said exogenous nucleic acid is expressed in said ocular [tissue] cell.

24. (Once Amended) A method of [alleviating] treating an ocular wound, said method comprising directly contacting an exogenous nucleic acid and an ocular cell *in situ* under conditions permissive for the direct uptake of said exogenous nucleic acid by said ocular cell, said exogenous nucleic acid encoding a protein useful in alleviating said ocular wound, whereby said exogenous nucleic acid is expressed in said ocular [tissue] cell.